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Applicant's or agent's file reference 11423PC2-MAH/AM	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001527	International Filing Date (day/month/year) 14 November 2003	Priority Date (day/month/year) 14 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 9/00		
Applicant QUEENSLAND UNIVERSITY OF TECHNOLOGY et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13 April 2004	Date of completion of the report 2 December 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer STEPHEN CLARK Telephone No. (02) 6283 2781

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages 1-3,6-12 as originally filed,
pages ,4 received on 19 August 2004 with the letter of 18 August 2004
pages ,5 received on 29 September 2004 with the letter of 28 September 2004
- ☒ the claims, pages , as originally filed,
pages ,13 received on 19 August 2004 with the letter of 18 August 2004
pages ,14 received on 29 September 2004 with the letter of 28 September 2004,
pages ,15-16 received on 24 November 2004 with the letter of 24 November 2004
- ☒ the drawings, pages 1,2 as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-29	YES
	Claims	NO
Inventive step (IS)	Claims 1-29	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

None of the citations alone, or in obvious combination, disclose all of the features of any of the claims.

In particular, none of the citations were used to inhibit myopia development in human beings. Although many of the citations treated myopia in a similar way, they did not disclose inhibiting development.

The features of exposing the eyes to a strobing or flashing light or pattern at a particular frequency and for a selected period were mostly disclosed in the citations but the particular frequency of 1 to 60 Hz and the feature of a feedback means for measuring myopia and adjusting the period and frequency of the light were not found.

It is to be noted that the frequency range was not common to all claims, nor was the feedback means, and, apart from the inhibiting feature, these claims could potentially be regarded as lacking unity of invention.

form, the invention resides in a method of inhibiting myopia development in a human subject including the steps of:

exposing the eyes of a subject to strobing or flickering light or pattern at a frequency in the range of greater than 1 Hz to about 60 Hz.

5 The method preferably includes the steps of prescribing a frequency and exposure time of the strobing or flickering light or pattern; and

treating the subject with the strobing or flickering light or pattern at the prescribed frequency and exposure time.

Preferably the treatment is repeated as required, such as daily.

10 Preferably, the method also includes the step of measuring the myopia of the subject.

By 'inhibiting' it is meant that the treatment reduces the advance of existing myopia and may prevent development of myopia if treated before onset.

15 Preferably the treatment occurs each day or each alternate day for at least ten minutes per treatment..

Preferably, the method includes a feedback loop for adjusting the treatment in response to the effectiveness of the treatment in terms of measured progress of the subject.

20 Preferably, the treatment is applied during daylight hours.

The treatment will preferably involve visible light (excluding ultraviolet and infrared) and may exclude short wavelengths (blue light).

In another form, the invention resides in an apparatus for inhibiting myopia developments in human subjects comprising:

a strobable light;

a means of adjusting a frequency at which the light strobes;

5 a means of adjusting a period of time over which the light strobes; and
such that said light strobes at a desired frequency for a desired time period; and

a feedback means of measuring myopia and making an adjustment to the period of time and the frequency the light strobes in response to the
10 measured myopia.

Suitably, the apparatus operates at a frequency in the range 1 to 60 Hz.

Most preferably, the frequency used is in the range 5 to 20 Hz.

Generally the frequency used will compensate for the frequency of the
15 background lighting.

Suitably, the time period will last for at least five minutes each day, or preferably ten or twenty minutes each day.

Most preferably the treatment will be applied for 5 or 10 minute periods every hour over a 2 to 10 hour period.

20 Generally the intensity of the light used will compensate for the intensity of the background lighting.

Most preferably, the wavelength of the light will be about 550 nm.

Suitably the wavelength of light will be selected to compensate for the

CLAIMS

1. A method of inhibiting myopia development in a human subject including the steps of:

5 exposing the eyes of a person to strobing or flashing light or pattern at a frequency in the range of greater than 1 Hz up to about 60 Hz for a selected period.

2. The method of claim 1 further including the steps of: prescribing a frequency and exposure time of the strobing or flickering light or pattern; and

10 treating the subject with the strobing or flickering light or pattern at the prescribed frequency and exposure time.

3. The method of claim 1 wherein the step of treating occurs for at least ten minutes each treatment.

15 4. The method of claim 1 further including the step of measuring the myopia of the subject.

5. The method of claim 1 wherein the step of exposing occurs each day or each alternate day.

20 6. The method of claim 1 further including the step of selecting the wavelength of the light, the intensity of the light, the frequency of flashing and the duration of flashing.

7. The method of claim 1 further including the step of recording feedback and using a feedback loop to adjust the treatment response to the effectiveness of the treatment in terms of measured progress of the subject.

8. The method of claim 4 wherein the light flashes at a frequency in the range between 5 and 20 Hz.
9. The method of claim 4 wherein the step of exposing is applied for at
5 least 5 minute periods every hour over a 2 to 10 hour period.
10. The method of claim 4 wherein the step of exposing is applied for 10 minute periods every hour over a 2 to 10 hour period.
11. The method of claim 4 wherein the step of exposing is applied for at least 20 minute periods every hour over a 2 to 10 hour period.
- 10 12. The method of claim 4 wherein the step of exposing is applied during daylight hours.
13. The method of claim 4 wherein the light is visible light.
14. An apparatus for inhibiting myopia development in humans comprising:
- 15 a strobable light;
a means of adjusting a frequency at which the light strobes;
a means of adjusting a period of time over which the light strobes
such that said light strobes at a desired frequency for a desired time
period; and
- 20 a feedback means of measuring myopia and making an adjustment to the period of time and the frequency the light strobes in response to the measured myopia.
15. The apparatus of claim 14 wherein the light is in the visible range.

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15. The apparatus claim 14 wherein the light is in the visible range.

16. The apparatus of claim 14 further comprising means for adjusting a wavelength of said strobable light.

5 17. The apparatus of claim 16 wherein the wavelength of the light is about 550 nm.

18. The apparatus of claim 14 wherein the strobable light is a light emitting diode.

19. The apparatus of claim 14 wherein the strobable light operates at a frequency in the range 5 to 20 Hz.

10 20. The apparatus of claim 14 wherein the frequency of the strobable light compensates for the frequency of the background lighting.

21. The apparatus of claim 14 wherein the intensity of the strobable light compensates for the intensity of the background lighting.

15 22. The apparatus of claim 14 wherein the wavelength of the strobable light compensates for the wavelength of the background light.

23. The apparatus of claim 14 further comprising a base.

24. The apparatus of claim 23 wherein the base is in the form of eyeglass frames with the light located near the hinge.

25. The apparatus of claim 23 wherein the base is mountable to a table.

20 26. The apparatus of claim 24 wherein said pattern flickers at a desired frequency for a desired time period.

27. An apparatus for inhibiting myopia development in humans comprising:

a flickering pattern of low luminance and high luminance regions;

25 a means of adjusting a frequency at which the pattern flickers in the

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range from greater than 1Hz to about 60 Hz; and

a means of adjusting a period of time over which the pattern flickers;

wherein said pattern flickers at a desired frequency for a desired time period and

5 a feedback means for measuring myopia and making an adjustment to the period of time over which the pattern flickers and the frequency at which the pattern flickers in response to the measured myopia.

28. The apparatus of claim 27 comprising a television frequency signal generator that delivers a television frequency signal of the flickering pattern.

10 29. The apparatus of claim 27 comprising a computer when programmed to display the flickering pattern on a monitor or screen of said computer.

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